CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.

COUNSELLORS AT LAW

CHARLES C. CARELLA BRENDAN T. BYRNE PETER G. STEWART ELLIOT M. OLSTEIN ARTHUR T. VANDERBILT, II JAN ALAN BRODY JOHN M. AGNELLO CHARLES M. CARELLA JAMES E. CECCHI JAMES T. BYERS
DONALD F. MICELI
A. RICHARD ROSS
KENNETH L. WINTERS
JEFFREY A. COOPER
CARL R. WOODWARD, III
MELISSA E. FLAX
DENNIS F. GLEASON
DAVID G. GILFILLAN
G. GLENNON TROUBLEFIELD
BRIAN H. FENLON
LINDSEY H. TAYLOR

5 BECKER FARM ROAD ROSELAND, N.J. 07068-1739 PHONE (973) 994-1700 FAX (973) 994-1744 www.carellabyrne.com

RICHARD K. MATANLE, II FRANCIS C. HAND AVRAM S. EULE RAYMOND W. FISHER

OF COUNSEL

RAYMOND J. LILLIE
WILLIAM SQUIRE
ALAN J. GRANT°
STEPHEN R. DANEK
ERIC MAGNELLI
DONALD A. ECKLUND
AUDRA E. PETROLLE
MEGAN A. NATALE
AMANDA J. BARISICH
°MEMBER N.Y. BAR ONLY

JAMES D. CECCHI (1933-1995) JOHN G. GILFILLAN III (1936-2008) December 5, 2011

Via ECF and Federal Express

Honorable Dennis M. Cavanaugh, U.S.D.J. United States District Court Martin Luther King Building & U.S. Courthouse Room PO-04 50 Walnut Street Newark, NJ 07101

Re: Eli Lilly and Co. v. Actavis et al., No. 07-3770 (D.N.J.) (DMC) (JAD)

Dear Judge Cavanaugh:

We, along with Rakoczy Molino Mazzochi Siwik LLP, represent Defendant Aurobindo Pharma Ltd. in the above-captioned matter.

We write jointly on behalf of Defendants Aurobindo Pharma Ltd., Sun Pharmaceutical Industries Limited, Sandoz, Inc., Mylan Pharmaceuticals, Inc., and Apotex Inc., and Plaintiff Eli Lilly and Company, regarding Plaintiff's motion for entry of final judgment, filed on November 1, 2011. (D.I. # 740). After conferring, the six aforementioned parties have reached an agreement regarding the proposed form of Final Judgment, which is enclosed herewith.¹

If the Court finds the enclosed acceptable, the six parties identified herein request that the Court enter the attached form of Final Judgment in the above-captioned matter.

Thank you for your attention to and consideration of this matter.

Respectfully yours,

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO

MELISSA E. FLAX

MEF

Enclosure

Cc: Counsel of Record (via ECF and email)

¹ Actavis Elizabeth LLC, and Teva Pharmaceuticals USA, Inc. did not join in these discussions, and this correspondence is not submitted in their behalf.

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY,)
Plaintiff,) Civil Action No. 07-3770 (DMC)(JAD)
V.))
ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC.))))))))))))))))
Defendants.)))

FINAL JUDGMENT

THIS MATTER having been remanded to this Court by the United States Court of Appeals for the Federal Circuit, the Court holds that the claims of Eli Lilly and Company's ("Lilly's") United States Patent No. 5,658,590 ("the '590 patent") are neither invalid nor unenforceable. The Court further finds that Sun Pharmaceutical Industries Limited, Sandoz, Inc., Mylan Pharmaceuticals, Inc., Apotex Inc., Aurobindo Pharma Ltd., Actavis Elizabeth LLC, and Teva Pharmaceuticals USA, Inc. (collectively, "Defendants") have infringed and threaten in the future to infringe claims 1-16 of the '590 patent. Accordingly:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT

1. Final Judgment is entered in favor of Lilly and against Defendants, with the '590 patent having been found to be not invalid and not unenforceable, and Defendants having been found liable for infringement. All remaining claims and counterclaims are dismissed;

- 2. Pursuant to 35 U.S.C. § 271(e)(4)(A) and 21 U.S.C. § 355a(b)(1)(B), which provides Lilly with a period of pediatric exclusivity with respect to its atomoxetine products running for six months after the date of expiration of the '590 patent, the effective date of any approval of the atomoxetine products that are the subject of Defendants' Abbreviated New Drug Application (ANDA) Nos. 78-940, 78-983, 79-016, 79-018, 79-020, 79-021, and 79-022 SHALL NOT occur until after May 26, 2017, and to the extent any of those ANDAs have received final approval, the United States Food and Drug Administration SHALL reset the effective date of approval of those ANDAs to a date after May 26, 2017;
- 3. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Defendants and their officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them are PERMANENTLY ENJOINED from the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the atomoxetine products that are the subject of their ANDAs or any atomoxetine product not colorably different therefrom during the term of the '590 patent, including any extensions under 35 U.S.C. § 156. This PERMANENT INJUNCTION ORDER is effective immediately upon the entry of this ruling on the Court's docket. Defendants are not prohibited from the commercial manufacture of atomoxetine products that are not the subject of Defendants' ANDAs solely for use, offer to sell or sale outside of the United States. Nothing in this judgment precludes Defendants from seeking regulatory approval for use of atomoxetine for uses other than to treat ADHD and for making, using, importing and selling product under such a regulatory approval solely for uses other than to treat ADHD.
- 4. Pursuant to Fed. R. Civ. P. 54(d)(1) and L. Civ. R. 54.1, Defendants shall pay Lilly its costs in an amount to be determined by this Court after considering the parties' briefs;

5.	The Court retains jurisdiction over Lilly and Defendants for purposes of enforcing
this Final Judg	gment; and

Clerk of the Court is directed to enter this Final Judgment forthwith.
ED.
DENNIS M. CAVANAUGH UNITED STATES DISTRICT HIDGE